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|--------------------------|-----------------|--------------|--|
| Interview Summary | Application No. | Applicant(s) | |
| | 09/877,933 | GRAY ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Ja-Na Hines. (3)_____.

(2) Nathan Cassell. (4)_____.

Date of Interview: 12 May 2005.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.

If Yes, brief description: _____.

Claim(s) discussed: Claims 5 and 32-33.

Identification of prior art discussed: N/A.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Atty Cassell agreed to having an examiner's amendment recite the necessary changes to obviate the objections and rejections of the claims. Atty Cassell also provided a draft amendment and response.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

TOWNSEND
and
TOWNSEND
and
CREW
LLP

San Francisco, California
Tel 415 576-0200

Walnut Creek, California
Tel 925 472-6000

San Diego, California
Tel 858 350-6100

Denver, Colorado
Tel 303 571-4000

Seattle, Washington
Tel 206 467-9500

Palo Alto

379 Lytton Avenue
Palo Alto
California 94301-1431
Tel 650-326-2400
Fax 650-326-2422

FACSIMILE COVER SHEET

| | | |
|---|---|---|
| Date: May 12, 2005 | Client & Matter Number: 014907-001910US | No. Pages (Including this one): 7 |
| To: Examiner Ja-Na Hines U.S.P.T.O. (Art Unit 1645) | At Fax Number: 571.273.0859 | Confirmation Phone Number: 571.272.0859 |
| From: Nathan S. Cassell | | (0459) |

Message:

Dear Examiner Hines:

Per our telephone conversation this afternoon, please see attached. This draft includes a slight change to claim 33, to address the two antibodies of the kit. If you have any questions or concerns, please do not hesitate to contact me.

Best regards,



| | | | | | |
|----------------|-----------------|------------------------------------|----------------------|---|-------------|
| Original Will: | BE SENT BY MAIL | BE SENT BY FEDEX/OVERNIGHT COURIER | BE SENT BY MESSENGER | X | NOT BE SENT |
|----------------|-----------------|------------------------------------|----------------------|---|-------------|

Faxed: Return to: **Nathan S. Cassell - (5285)**

If you have problems with reception please call Fax Services at extension 5565

Important

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and/or exempt from disclosure by applicable law or court order. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address via the United States Postal Service. Thank you.

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DRAFT

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On _____

TOWNSEND and TOWNSEND and CREW LLP

By: _____
Nancy Pizzo

**AMENDMENT UNDER 37 CFR 1.116
EXPEDITED PROCEDURE -
EXAMINING GROUP 1645**

PATENT

Attorney Docket No.: 014907-001910US

Customer No. 20350

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jeff Gray

Application No.: 09/877,933

Filed: June 7, 2001

For: **DIAGNOSTIC ASSAYS FOR
DETECTION OF CRYPTOSPORIDIUM
PARVUM**

Confirmation No. 1440

Examiner: Hines, J.

T.C./Art Unit: 1645

**AMENDMENT UNDER 37 CFR 1.116
EXPEDITED PROCEDURE -
EXAMINING GROUP 1645**

Mailstop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action mailed April 4, 2005 on the above-referenced application, please enter the following amendments and remarks:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

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Appl. No. 09/877,933
Amendment After Final dated May 12, 2005
AMENDMENT UNDER 37 CFR 1.116 EXPEDITED PROCEDURE
EXAMINING GROUP 1645

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Amendments to the Claims:

Claims 5, 32, and 33 are presently amended. This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (previously presented) A method of diagnosing infection of a mammal by a *Cryptosporidium* species, the method comprising:
contacting a stool sample obtained from the mammal with a capture reagent comprising an antibody which binds to *Cryptosporidium* protein disulfide isomerase, wherein the capture reagent forms a complex with the protein disulfide isomerase if the protein disulfide isomerase is present in the stool sample; and
detecting whether protein disulfide isomerase is bound to the capture reagent, wherein the presence of protein disulfide isomerase is indicative of *Cryptosporidium* infection of the mammal.
2. (previously presented) The method of claim 1, wherein the capture reagent comprises an antibody that specifically binds to the amino acid sequence AWFCGTNEDFAKYASNIRKVAADYREKYAFVF (SEQ ID NO: 3).
3. (previously presented) The method of claim 2, wherein the capture reagent comprises an antibody that specifically binds to the amino acid sequence of SEQ ID NO: 2.
4. (canceled)
5. (currently amended) The method of claim 1 1 [[4]], wherein the antibody is a recombinant antibody.

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6. (original) The method of claim 5, wherein the antibody is a recombinant polyclonal antibody.
7. (canceled)
8. (original) The method of claim 1, wherein the capture reagent is immobilized on a solid support.
9. (original) The method of claim 8, wherein the capture reagent is immobilized on the solid support prior to contacting the capture reagent with the test sample.
10. (original) The method of claim 1, wherein the detection of the protein disulfide isomerase is performed by contacting the protein disulfide isomerase with a detection reagent which binds to the protein disulfide isomerase.
11. (original) The method of claim 10, wherein the detection reagent comprises an antibody which binds to protein disulfide isomerase.
12. (original) The method of claim 10, wherein the detection reagent comprises a detectable label.
13. (original) The method of claim 12, wherein the detectable label is selected from the group consisting of a radioactive label, a fluorophore, a dye, an enzyme, and a chemiluminescent label.
14. (previously presented) A kit for diagnosing infection of a mammal by a *Cryptosporidium* species, the kit comprising:
 - a solid support upon which is immobilized a capture reagent comprising an antibody which binds to a protein disulfide isomerase of *Cryptosporidium parvum*; and
 - a detection reagent comprising an antibody which binds to the protein disulfide isomerase.

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15. (original) The kit according to claim 14, wherein the kit further comprises a positive control that comprises a protein disulfide isomerase.

16. (previously presented) The kit according to claim 15, wherein the capture reagent comprises an antibody that specifically binds to the amino acid sequence AWFCGTNEDFAKYASNIRKVAADYREKYAFVF (SEQ ID NO: 3).

17. - 31. (canceled)

32. (currently amended) The method of claim 1, wherein the antibody is comprises an antibody fragment.

33. (currently amended) The kit of claim 14, wherein at least one of the capture reagent antibody or the detection reagent antibody is comprises an antibody fragment.

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Appl. No. 09/877,933
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EXAMINING GROUP 1645

REMARKS/ARGUMENTS

Claims 1-3, 5, 6, 8-16, 32, and 33 are presently under consideration. Claims 5 and 6 are objected to, and claims 32 and 33 are substantively rejected. This response amends claims 5, 32, and 33. No new matter is introduced. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Office Action.

Claim Objections

¶3. Claims 5 and 6 were objected to for depending upon canceled claim 4. Claim 5 is presently amended to depend from claim 1. Claim 6 depends from claim 5. Withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. §112

¶3. Claims 32 and 33 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. This rejection is traversed in part and overcome in part as follows.

The Office Action alleges that the comprising language in claims 32 and 33 makes it unclear if the antibody further comprises an antibody fragment also, or if the antibody is an antibody fragment.

To expedite prosecution of the instant application notwithstanding the traverse, Applicant has amended claim 32 to recite a method wherein the antibody is an antibody fragment. A similar amendment is made to claim 33, and claim 33 is further amended to address the two antibodies recited in the claim (i.e. capture reagent antibody and detection reagent antibody). Withdrawal of this rejection is respectfully requested.

Applicant's Summary of Interview

Applicant thanks the Examiner for the courtesies extended in a telephonic conversation of March 31, 2005. Examiner Hines and Applicant's undersigned representative participated. In brief, claims 5, 6, 32, and 33 were discussed, and the above-noted objections and rejection were considered. No exhibits were shown, no demonstrations were conducted, and no

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references were discussed. An agreement was reached that the Examiner would send an office action detailing the objections and rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

Nathan S. Cassell
Reg. No. 42,396

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
NSC:nap
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